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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,608	06/18/2001	Alexandr Ivanovich Smikodub	205,209	2955

7590 04/15/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,608

Applicant(s)

SMIKODUB, ALEXANDR
IVANOVICH

Examiner

Joseph T. Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 national stage filing of PCT/AU98/00020, filed December 16, 1998.

Claims 1-7 are pending.

Election/Restrictions

Applicant's election of Group II is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-7, drawn to a method for treatment of a subject comprising administering hematopoietic spleen stem cells, and an additional suspension of cells selected from the group set forth in claim 1 are currently under examination.

It is noted that in the restriction requirement only claims 1-6 were indicated, however claims 1-7 were pending at the time of the restriction requirement. Claim 7 belongs to each of the restricted groups and was inadvertently omitted from each of the groups. Accordingly, it is included in the basis of examination of the elected group.

Claim Objections

Claim 1 is objected to because of the following informalities: Applicant has elected group II, comprising administering hematopoietic spleen stem cells. However, the claim still recites and encompasses the non-elected inventions.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,184,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '033 are drawn to a pharmaceutical composition for use in treatment that encompasses the same composition used in the instantly claimed methods. The use of the allowed compositions would be obvious over their methods of use as set forth in the preamble of the allowed claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 is unclear with respect to the amounts or concentrations contained in the suspension. It is noted that specific numbers are set forth, however there are not units. Further, the metes and bounds of 'nucleated cells' is indefinite because to what cells it is referring is unclear. Several cell types are set forth that should be delivered, it is unclear if the nucleated cells refer to all the cells in the composition, or additional cells beyond those specifically recited. Further, it is unclear if these are all embryonic cells, that is specific cell types comprised in the hematopoietic liver/spleen cells or cells from another source. The claims are unclear because the products and concentrations of the products contained in the suspension to be delivered are not clearly set forth. Finally, the claims are vague and incomplete because the condition or type of patient being treated is not clearly set forth. Moreover, the claims recite delivery of an additional suspension, however some of the cell types to be delivered are the same as those in the main composition. The claims are unclear because what state in a subject that is being treated is not clearly set forth nor are specific method steps for the delivery route or effective therapeutic amounts of the composition for any given condition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/16455.

As acknowledged by the present disclosure, WO 95/16455 provides the same compositions and use for treatment of AIDS. It is noted that the instant claims encompass treatment of a patient without setting forth any specific condition and can be fairly interpreted to encompass treating a patient with AIDS as set forth in WO 95/16455. Therefore, the instantly claimed methods are anticipated by those set forth in WO 95/16455.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Smikodub *et al.* (Lik Sprava. 1994 Mar-Apr;(3-4):104-8) teach the treatment of acquired aplastic anemia with hematopoietic cells from human embryonic liver.

Touraine *et al.* (Bone Marrow Transplant. 1992;9 Suppl 1:121-6) teach *in utero* transplantation of stem cells in humans and the immunological aspects and clinical follow-up of patients.

Each of the references demonstrate that at the time of filing methods for delivering embryonic cells were known and used in attempt to treat subjects in order to restore some capacity of the hematopoietic system. It is noted that the instant claims do not require any specific treatment to be affected only administration. The teachings of the above references provide evidence that the use of embryonic stem cells was actively sought for treatment of specific conditions in a subject.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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AU1632